

DOCKET NO.: C215
Application No.: 09/975,350
Office Action Dated: April 2, 2008

PATENT

REMARKS

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Status of ClaimsCurrent Status

Claims 1, 3, 4, 8-43, 45-50, 55-60 and 63-68 are pending. Claims 36-43, 56-58, 60, 64 and 65 are withdrawn from consideration. Claims 1, 3, 4, 8-43, 45-50, 55-60 and 63-68 are rejected.

Present Reply

In this reply claims 1, 15, 41 and 42 are amended, and claims 14, 67 and 68 are canceled. Upon entry of the present amendment, claims 1, 3, 4, 8-13, 15-43, 45-50, 55-60 and 63-66 will be pending in this application, with claims 36-43, 56-58, 60, 64 and 65 being withdrawn from consideration. No new matter has been added by way of these amendments.

Claim Rejections

Reconsideration and allowance of all claims is hereby respectfully requested in light of the following discussion.

Rejection under 35 U.S.C. §102

Claims 1, 3, 4, 11, 14, 15, 32, 33, 45-47, and 59 are rejected under 35 U.S.C. §102(b) as being anticipated by Nguyen et al. (US 5,843,347). The Examiner alleges that the lyophilized composition of Nguyen is a non-aqueous "solid solution."

As amended, the pending claims are directed to non-aqueous liquid solutions of modafinil containing at least one organic solvent. The teaching of Nguyen is limited to aqueous pasty mixtures containing ca. 50% water and solid lyophilizate particles prepared from the aqueous pasty mixtures (Abstract, Subject of the Invention, Examples 16-17). The aqueous pasty mixtures of Nguyen are not non-aqueous and do not contain an organic solvent as presently claimed. The solid lyophilizate particles of Nguyen are not liquid solutions and do not contain an organic solvent as presently claimed. Therefore, neither the aqueous pasty mixture nor the solid lyophilizate particles of Nguyen contain each limitation of the pending claims and Nguyen is not an anticipatory reference. Applicants respectfully request that this rejection be withdrawn.

Rejections under 35 U.S.C. §103

Nguyen:

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Claims 1, 3, 4, 8-35, 45-47, 55, 56, 59, 63, 66 and 68 are rejected under 35 U.S.C. §103(a) as being unpatentable over Nguyen et al. (US 5,843,347).

To establish a *prima facie* case of obviousness, the Examiner must demonstrate that a prior art reference teaches or suggests all of the limitations of the rejected claims (MPEP § 2142).

As discussed above, Nguyen is directed to aqueous pasty mixtures and solid lyophilizate particles prepared from the aqueous pasty mixtures. There is no motivation to modify the aqueous pasty mixtures or the solid lyophilizate particle compositions of Nguyen because Nguyen teaches that the aqueous pasty mixtures and lyophilized particles provide advantageous properties and a novel technical solution over the prior art (col. 2, line 45 to col. 3, line 27; col. 3, lines 38-50). And even if a person of ordinary skill was somehow motivated to depart from the teaching of Nguyen and prepare a non-aqueous modafinil solution containing at least one organic solvent and at least one surfactant, which spontaneously forms an aqueous, liquid, homogeneous, stable composition of non-crystalline particles when contacted with an aqueous medium, Nguyen provides no direction on how to prepare such a solution.

In view of the fact that Nguyen fails to teach or suggest a non-aqueous liquid solution containing modafinil and at least one organic solvent, Nguyen does not teach or suggest each limitation of the rejected claims and therefore cannot render the rejected claims obvious.

Applicants respectfully request that this rejection be withdrawn.

Nguyen and Grebow:

Claims 47-50, 55, 56, 67 and 68 are rejected under 35 U.S.C. §103(a) as being unpatentable over Nguyen et al. (US 5,843,347) in view of Grebow (US 5,618,845). The Examiner alleges that Nguyen teaches as above and Grebow teaches encapsulation.

As discussed above, Nguyen does not teach or suggest a non-aqueous liquid solution containing modafinil and at least one organic solvent. Grebow fails to cure the deficiencies of Nguyen. The Grebow reference is concerned with discrete solid particles, not solutions. Specifically, the Grebow reference is directed to a pharmaceutical composition comprising discrete modafinil particles having a defined particle size (col. 2, lines 6-8), which is important to the potency and safety of the drug (col. 2, lines 8-10). There is no motivation to modify the Grebow disclosure to form a modafinil solution because such a modification would dissolve and

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thus destroy the solid modafinil particles of defined particle size, which Grebow discovered to be important to the potency and safety of the drug (col. 4, lines 53-55). Modifying Grebow to dissolve the solid modafinil particles would require a fundamental departure from the reference. Accordingly, Grebow does not cure the deficiencies of Nguyen.

In view of the fact that Nguyen and Grebow fail to teach or suggest a non-aqueous liquid solution of modafinil and at least one organic solvent, Nguyen and Grebow do not teach or suggest each limitation of the rejected claims and therefore cannot render the rejected claims obvious. Applicants respectfully request that this rejection be withdrawn.

Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. It is believed that all the claims are in form for allowance, and an early notification to that end is respectfully requested. Applicants invite the Examiner to contact the undersigned at (610) 883-5679 to clarify any remaining issues.

Respectfully submitted,



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